

**REMARKS & ARGUMENTS**

Claims 1-5, 7-19, and 21-22 are pending in the present application. Claims 6 and 20 were previously canceled. Independent claims 1, 7, and 16 are amended herein. Applicants affirm that no new subject matter is added to the present application by way of this Amendment. Applicants submit that the claims as amended are allowable over the prior art of record. Accordingly, reconsideration and an early Notice of Allowance are respectfully requested.

Claims 1-5, 7-14, and 16-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Epstein et al. (U.S. Pat. No. 5,464,392) in view of Pastrone et al. (U.S. Pat. No. 4,453,931) as applied to claims 6-14 and 20-22 in the first office action. Claim 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Epstein et al. in view of Pastrone et al. as applied to claim 7 in the second office action, and further in view of Das et al. (U.S. Pat. App. No. 2002/0128594 A1).

Claims 1, 7, and 16 are currently amended to more clearly distinguish the present invention from the disclosures of Epstein et al., Pastrone et al., Das et al., and the other references of record. Support for Applicants' amendments is found throughout the present application as originally filed including, for purposes example but not for purposes of limitation, in Figs. 1, 4, and 5, and paragraphs 39, 51 through 55, and 63 through 65, among other sections.

In contrast to Applicants' claimed invention, Epstein's pressure transducer 40 is limited to be "operatively connected to the pressure chamber 22" proximate to pressure transducer receiving aperture 242. In further contrast to the instant invention, Epstein's transducer 40 teaches away from the claimed invention because Epstein does not have any direct pressure sensor connection to the pumping actuator 46 or the pumping piston receiving aperture 240. See, FIG. 4B and disclosure at col. 6, lines 12-13, and col. 16, lines 56-59.

Unlike the invention claimed in the present application, Pastrone's disclosure is restricted to a "pressure transducer 57 suspended within a fluid medium 59, preferably a silicon gel" that measures "force exerted on the diaphragm member 55 by the internal piston head 53." Pastrone et al. teaches away from the claimed invention with the

indirect pressure sensing arrangement of the fluid-suspended pressure transducer. Pastrone et al. is limited to indirect pressure sensing of the Pastrone pumping piston 51 or the internal piston head 53. Additionally, the Pastrone piston head 53 is movably "forced against upward against internal diaphragm member 55." The movement of the piston head 53 relative to the pumping piston 51 is also shown in Fig. 3. See, Pastrone's Fig. 3 and col. 3, lines 8-15.

The Das et al. application only describes a bolus or basal infusion pump that incorporates a force sensor 16 mounted on a unidirectional drive screw 15 to actuate a syringe 12 filled with medication to be delivered in large amounts to a patient. See, Fig. 1 and paragraphs 33 and 43. In contrast to the present invention, the Das et al. device does not teach or suggest and is not directed to Applicants' claimed pumping element having a piston head and a main body and a pressure sensor.

Applicant's submit that Pastrone et al. is devoid of any suggestion or motivation to combine his fluid-suspended pressure transducer 57 to be in direct contact with a fluid pressure chamber or piston in a configuration such as that disclosed by Applicants or Epstein et al. Similarly, the Epstein et al. disclosure, as well as the other references on record, do not offer any motivation or suggestion to those skilled in the art to incorporate a Pastrone type of fluid-suspended pressure transducer. Additionally, neither does Das et al. offer any suggestion or motivation to combine its force sensor device and screw drive with the infusion pump pistons of either Epstein, Pastrone, or the others of record.

Applicant's note for purposes of illustration that even if one skilled in the art was tempted to combine Pastrone's fluid-suspended pressure transducer arrangement in an Epstein pressure transducer receiving aperture or in a device according to Das et al., the result would not be the presently claimed invention. Also, the combination would not operate either as claimed by Applicants or as intended by either Epstein or Pastrone or Das. Instead, the proposed combination of Epstein or Das with the Pastrone fluid suspended pressure transducer arrangement will result in unnecessary pressure reading inaccuracies and errors.

Those skilled in the art may recognize that pressure reading errors or inaccuracies will result from temperature gradients between the fluid flowing through the

pump, and the Pastrone diaphragm and fluid medium or silicon gel. Other inaccuracies will result from the fluid mechanics and harmonics inherent in the combination of the Pastrone movable piston head, diaphragm, fluid medium, and fluid-suspended pressure transducer. This combination produces a complex mechanical system with vibrational characteristics that can unexpectedly vibrate and randomly increase and attenuate pressure forces, which leads to inaccurate or erroneous pressure readings.

Using the presently claimed invention as a roadmap, those skilled in the art should comprehend that the Pastrone et al. movable piston head, diaphragm, and fluid-suspended pressure transducer components also introduce undesirable and unnecessary manufacturing and maintenance challenges. These, in turn, teach away from the present invention and add production and operational impediments and costs.

Unlike the proposed combination of Epstein, Pastrone, and or Das, and the other references of record, Applicants' invention of amended claims 1, 7, and 16 is directed to a medical pump that includes, among other features:

- (1) a pumping element adapted to forcibly press on and intermittently pressurize the pumping chamber during a pumping cycle, wherein the pumping element includes a piston head connected to a main body, and
- (2) a pressure sensor rigidly connected in a force bearing relationship to at least one of the piston head and the main body.

Applicants' invention is further distinguished over the art of record, including Das et al., in claim 15 where the recited pressure sensor is a force sensor and is the only pressure sensor included in the medical pump.

## **CONCLUSION**

In view of these considerations and the current amendments to claims 1, 7, and 16, and the preceding discussion, Applicants' submit that Epstein et al. in combination with Pastrone et al. and Das et al., or any of the other references of record, fail to render claims 1-5, 7-19, and 21-22 obvious to those having ordinary skill in the art. Accordingly, Applicants' submit that the pending claims as amended are in condition for allowance and request a Notice of Allowance be issued at the earliest opportunity.

Applicants' undersigned representative invites the examiner to contact him directly at (847) 935-1771 with any questions or inquiries as well as suggestions that may favorably advance prosecution.

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